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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/720,037 | 12/20/2000 | Eric Raspe | MERCK-2179 | 7082 |

23599 7590 06/18/2008
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| EXAMINER |
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SHAFFER, SHULAMITH H

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| ART UNIT | PAPER NUMBER |
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1647

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| MAIL DATE | DELIVERY MODE |
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06/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--|-------------------------------------|--|
| Office Action Summary | Application No. 09/720,037 | Applicant(s) RASPE ET AL. | |
| | Examiner SHULAMITH H. SHAFER | Art Unit 1647 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4-7-08.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-13 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
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| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' amendment to the claims as submitted on 7 April 2008 is acknowledged and made of record. Claims 1-9 are amended. Claims 10-13 are newly submitted. Claims 1-13 are pending in the instant application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3, and 9-13, as drawn to a method of screening for a substance useful in the treatment of a lipid metabolism dysfunction comprising contacting said substance with a Rev-erb receptor.

Group II, claim(s) 1-3, and 9-13, as drawn to a method of screening for a substance useful in the treatment of a lipid metabolism dysfunction comprising contacting said substance with a Rev-erb response element.

Group III, claim(s) 3, and 9-13, as drawn to a method of screening for a substance useful in the treatment of a lipid metabolism dysfunction comprising contacting said substance with a nuclear factor capable of functionally coupling Rev-erb to the RNA polymerase complex.

Group IV, claim(s) 4, drawn to a method for screening for a substance useful in the treatment of a lipid metabolism dysfunction, comprising determining the effect of the test substance on the modulation of the expression of the gene coding for the Rev-erb receptor.

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Group V, claim(s) 5, and 6 as drawn to a method for preparation of a pharmaceutical composition useful in the treatment and/or prevention of a lipid metabolism dysfunction comprising a substance identified as capable of binding to the Rev-erb receptor.

Group VI, claim(s) 5 and 6, as drawn to a method for preparation of a pharmaceutical composition useful in the treatment and/or prevention of a lipid metabolism dysfunction comprising a substance identified as capable of binding to the Rev-erb response element.

Group VII, claim(s) 7, drawn to a method for preparation of a pharmaceutical composition useful in the treatment and/or prevention of a lipid metabolism dysfunction comprising a substance which is capable of modulating the transcriptional activity of a gene under control of a promoter comprising the Rev-erb receptor response element.

Group VIII, claim(s) 8, drawn to method of preparing a composition which is useful for the treatment and/or prevention of lipid metabolism dysfunctions comprising a substance which is capable of modulating expression of a gene coding for the Rev-erb receptor.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: multiple distinct processes are claimed (see also MPEP 1850). The methods are distinct from each other in having different goals (screening for substances, preparation of pharmaceutical compositions), recite different steps and would identify different compounds.

Group I is drawn to a screening method utilizing a Rev-erb receptor, a limitation not required by the screening methods of Groups I-IV.

Group II is drawn to a screening method utilizing a Rev-erb response element, a limitation not required by the screening methods of Groups I, III or IV.

Group III is drawn to a screening method utilizing a nuclear factor capable of functionally coupling Rev-erb to the RNA polymerase complex a limitation not required by the screening methods of Groups I, II or IV.

Group IV is drawn to a screening method comprising measuring modulation of the expression of the gene coding for the Rev-erb receptor, a limitation not required by screening methods of Groups I-III.

Groups V-VIII are drawn to methods of preparing pharmaceutical compositions comprising compounds of different functions. One of ordinary skill in the art would protect that these compounds would also have different structural characteristics.

Under lack of unity rules, applicant is entitled to examination of the first product, the first method of making the product, and the first method of using the product, if each of these first products and processes are present in the claims.

However, the claims of the instant invention do not recite any products, or methods of making said products. Thus, under lack of unity rules, Invention I will comprises the first claimed method, which recites a method of screening comprising contacting a test substance with a Rev-erb receptor, a method step not required by any of the other inventions.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the

requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHULAMITH H. SHAFER whose telephone number is (571)272-3332. The examiner can normally be reached on Monday through Friday, 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao, Ph.D. can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shulamith H. Shafer, Ph.D./

Examiner, Art Unit 1647

/Manjunath N. Rao, /

Supervisory Patent Examiner, Art Unit 1647

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| Application Number  | Application/Control No. | Applicant(s)/Patent under Reexamination | |
| | 09/720,037 | RASPE ET AL. | |
| | Examiner | Art Unit | |
| | SHULAMITH H. SHAFER | 1647 | |